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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/680,956	10/08/2003	Matthias Finckh	930008-2113	6079

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FROMMER LAWRENCE & HAUG
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EXAMINER	
GHALI, ISIS A D	
ART UNIT	PAPER NUMBER
1615	
MAIL DATE	DELIVERY MODE
07/13/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/680,956	FINCKH ET AL.	
	Examiner	Art Unit	
	Isis A. Ghali	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 May 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3 and 5-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3, 5-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *05/14/2007*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The receipt is acknowledged of applicants' IDS and amendment, both filed 05/14/2007.

Claim 4 has been canceled, and claims 13-20 have been added.

Claims 1-3, and 5-20 are pending and included in the prosecution.

The following rejections and objections have been overcome by virtue of applicants' amendment and remarks:

(A) Objections made to the specification.

(B) Objection to the claims for including minor informalities.

(C) Rejection of claims 4, and 9-12 under 35 U.S.C. 112, second paragraph, as being indefinite.

The following rejections have been discussed in details in the previous office action, and are maintained for reasons of record:

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

3. Claims 1-3, and 5-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over any of WO 93/23025 ('025) in view of JP 61-129117 ('117) and US 6,198,017 ('017).

WO '025 teaches transdermal patch to deliver oxybutynin comprising backing layer, matrix comprising the oxybutynin in an adhesive polymer and permeation enhancer, and a release liner (abstract; page 7, lines 17-30; figure 1). The size of the patch ranges from 5-50 cm^2 (page 13, lines 21-23).

WO '025 does not teach the aloe vera in the composition or the cross-linking agent as claimed by claims 1 and 5. The reference does not teach the acrylic adhesive as claimed in claim 4, the vegetable oil used to extract the aloe vera and its amount as

claimed in claims 6 and 7, or the amount of different ingredients as claimed in claims 9-11.

JP '117 teaches cataplasm composition containing aloe vera extract in an amount of equal or more than 5 wt% of the whole composition to provide high permeability of the main drug component to the skin and meanwhile provides improved viscoelastic properties, stability, and preferable adhesiveness to the skin leaving no residual on the skin after the use of the cataplasm (see the provided abstract).

US '017 teaches medical pressure sensitive adhesive comprising acrylic adhesive cross-linked with 2.5% of aluminum acetylacetonate providing excellent adherence to wet and dry skin and can be removed from the skin without residue (abstract; col.2, lines 3-12; col.3, lines 16-18).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide a transdermal device to deliver oxybutynin comprising polymer adhesive matrix comprising the drug and permeation enhancer as disclosed by WO '025, and replace the permeation enhancer with aloe vera extract disclosed by JP '117, motivated by the teaching of JP '117 that aloe vera extract provides high permeability of the main drug component to the skin and meanwhile provides improved viscoelastic properties, stability, and preferable adhesiveness to the skin leaving no residual on the skin after use, with reasonable expectation of having transdermal device to deliver oxybutynin comprising polymer adhesive matrix comprising oxybutynin and aloe vera extract that provides high permeability of oxybutynin to the skin, improved viscoelastic properties, stability, and preferable

adhesiveness to the skin leaving no residual on the skin after use of the polymer adhesive matrix.

Additionally, one having ordinary skill in the art at the time of the invention would have used acrylic adhesive cross-linked with aluminum acetylacetonate as a polymer matrix as disclosed by US '017, motivated by the teaching of US '017 that acrylate adhesive cross-linked with aluminum acetylacetonate provides excellent adherence to wet and dry skin and can be removed from the skin without residue, with reasonable expectation of having transdermal device to deliver oxybutynin comprising cross-linked acrylic adhesive matrix that has been cross-linked with aluminum acetylacetonate that provides excellent adherence to wet and dry skin and can be removed from the skin without residue providing comfortability and pleasance to the user.

The combination of the references does not teach the amount of the drug as instantly claimed by claim 9, the vegetable oil used to extract the aloe vera and its amount as claimed in claims 6 and 7.

The claimed amount does not impart patentability to the claims, absent evidence to the contrary.

The oil-based aloe vera extract is step directed to method of extraction of the aloe vera and the method of extraction of the aloe vera does not impart patentability to the product claims. The source of aloe vera does not impart patentability to the claims, absent evidence to the contrary.

Response to Arguments

4. Applicant's arguments filed 05/14/2007 have been fully considered but they are not persuasive.

Applicants argue that WO '025 in page 5, line 26 till page 6, line 15, teaches that the permeation enhancer effective to one drug may not be effective to another, and permeation enhancers interact adversely with other components of transdermal devices and can cause compatibility problems.

With careful review to page 5 and 6 of the reference, no such disclosure has been found.

Applicants argue that there is no motivation to combine the teachings of WO '025 with JP '117 because WO '025 teaches away from using permeation enhancers not in the reference, and therefore, no expectation of success is expected.

In response to this argument, and in considering the disclosure of the reference, it is proper to take into account not only the specific teachings of the reference but also the inferences which one skilled in the art would reasonably be expected to draw therefrom. *In re Preda*, 401 F.2d 825, 826, 159 USPQ 342, 344 (CCPA 1968). The rational to modify or to combine the prior art does not have to be expressly stated in the prior art; the rational may be expressly or impliedly contained in the prior art or it may be reasoned from knowledge generally available to one of ordinary skill in the art. The reason or motivation to modify the reference may often suggest what the inventor has done, but for a different purpose or to solve different problem. It is not necessary that the prior art suggest the combination or modification to achieve the same advantage or result discovered by applicant. *In re Linter*, 458 F.2d 1013, 173 USPQ 560 (CCPA

1972). In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide a transdermal device to deliver oxybutynin comprising polymer adhesive matrix comprising the drug and permeation enhancer as disclosed by WO '025, and replace the permeation enhancer with aloe vera extract disclosed by JP '117, motivated by the teaching of JP '117 that aloe vera extract provides high permeability of the main drug component to the skin and meanwhile provides improved viscoelastic properties, stability, and preferable adhesiveness to the skin leaving no residual on the skin after use, with reasonable expectation of having transdermal device to deliver oxybutynin comprising polymer adhesive matrix comprising oxybutynin and aloe vera extract that provides high permeability of oxybutynin to the skin, improved viscoelastic properties, stability, and preferable adhesiveness to the skin leaving no residual on the skin after use of the polymer adhesive matrix. WO '025 does not teach away from using *aloe vera*, as asserted by applicants. JP '117 teaches *aloe vera* suitable for drugs in general and not specific drugs and not others.

It is well established that the claims are given the broadest interpretation during examination. A conclusion of obviousness under 35 U.S.C. 103 (a) does not require absolute predictability, only a reasonable expectation of success; and references are evaluated by what they suggest to one versed in the art, rather than by their specific disclosure. *In re Bozek*, 163 USPQ 545 (CCPA 1969).

In the light of the foregoing discussion, the Examiner's ultimate legal conclusion is that the subject matter defined by the claims would have been *prima facie* obvious within the meaning of 35 U.S.C. 103 (a).

5. Claims 1-3, and 5-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over any of US 5,602,839 ('839) in view of JP 61-129117 ('117) and US 6,198,017 ('017).

US '839 teaches transdermal patch to deliver oxybutynin comprising backing layer, matrix comprising the 20% oxybutynin in cross-linked acrylic adhesive polymer and 10-20% permeation enhancer, and a release liner (abstract; col.4, lines 1-5; col.6, lines 59-60;col.7, lines 5, 28, 51; col.9, lines 60-67).

US '839 does not teach the aloe vera in the composition as claimed by claim 1 or the specific cross-linking agent as claimed by claim 5. The reference does not teach the vegetable oil used to extract the aloe vera and its amount as claimed in claims 6 and 7, the amount the cross-linking agent as claimed in claim 11, or the size of the patch as claimed in claim 12.

JP '117 teaches cataplasm composition containing aloe vera extract in an amount of equal or more than 5 wt% of the whole composition to provide high permeability of the main drug component to the skin and meanwhile provides improved viscoelastic properties, stability, and preferable adhesiveness to the skin leaving no residual on the skin after the use of the cataplasm (see the provided abstract).

US '017 teaches medical pressure sensitive adhesive comprising acrylic adhesive cross-linked with 2.5% of aluminum acetylacetonate providing excellent adherence to wet and dry skin and can be removed from the skin without residue (abstract; col.2, lines 3-12; col.3, lines 16-18).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide a transdermal device to deliver oxybutynin comprising cross-linked acrylic adhesive matrix comprising the drug and permeation enhancer as disclosed by US '839, and replace the permeation enhancer with aloe vera extract disclosed by JP '117, motivated by the teaching of JP '117 that aloe vera extract provides high permeability of the main drug component to the skin and meanwhile provides improved viscoelastic properties, stability, and preferable adhesiveness to the skin leaving no residual on the skin after use, with reasonable expectation of having transdermal device to deliver oxybutynin comprising cross-linked acrylic adhesive matrix comprising oxybutynin and aloe vera extract that provides high permeability of oxybutynin to the skin, improved viscoelastic properties, stability, and preferable adhesiveness to the skin leaving no residual on the skin after use of the polymer adhesive matrix.

Additionally, one having ordinary skill in the art at the time of the invention would have used acrylic adhesive cross-linked with aluminum acetylacetonate as an adhesive polymer for the matrix as disclosed by US '017, motivated by the teaching of US '017 that acrylate adhesive cross-linked with aluminum acetylacetonate provides excellent adherence to wet and dry skin and can be removed from the skin without residue, with reasonable expectation of having transdermal device to deliver oxybutynin comprising cross-linked acrylic adhesive matrix that has been cross-linked with aluminum acetylacetonate that provides excellent adherence to wet and dry skin and can be removed from the skin without residue providing comfortability and pleasance to the user.

The combination of the references does not teach the vegetable oil used to extract the aloe vera and its amount as claimed in claims 6 and 7, or the size of the patch as claimed in claim 12.

The oil-based aloe vera extract is step directed to method of extraction of the aloe vera and the method of extraction of the aloe vera does not impart patentability to the product claims. The source of aloe vera does not impart patentability to the claims, absent evidence to the contrary.

The size of the patch does not impart patentability to the claims, absent evidence to the contrary.

Response to Arguments

6. Applicant's arguments filed 05/14/2007 have been fully considered but they are not persuasive. Applicants argue that no motivation to combine the transdermal patch of US '839 with the enhancer of JP '117, given the idiosyncratic nature of permeation enhancers.

In response to this argument, and in considering the disclosure of the reference, it is proper to take into account not only the specific teachings of the reference but also the inferences which one skilled in the art would reasonably be expected to draw therefrom. *In re Preda*, 401 F.2d 825, 826, 159 USPQ 342, 344 (CCPA 1968). The rational to modify or to combine the prior art does not have to be expressly stated in the prior art; the rational may be expressly or impliedly contained in the prior art or it may be reasoned from knowledge generally available to one of ordinary skill in the art. The reason or motivation to modify the reference may often suggest what the inventor has done, but for a different purpose or to solve different problem. It is not necessary that the prior art suggest the combination or modification to achieve the same advantage or result discovered by applicant. *In re Linter*, 458 F.2d 1013, 173 USPQ 560 (CCPA 1972). In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, it would have

been obvious to one having ordinary skill in the art at the time of the invention to provide a transdermal device to deliver oxybutynin comprising cross-linked acrylic adhesive matrix comprising the drug and permeation enhancer as disclosed by US '839, and replace the permeation enhancer with aloe vera extract disclosed by JP '117, motivated by the teaching of JP '117 that aloe vera extract provides high permeability of the main drug component to the skin and meanwhile provides improved viscoelastic properties, stability, and preferable adhesiveness to the skin leaving no residual on the skin after use, with reasonable expectation of having transdermal device to deliver oxybutynin comprising cross-linked acrylic adhesive matrix comprising oxybutynin and aloe vera extract that provides high permeability of oxybutynin to the skin, improved viscoelastic properties, stability, and preferable adhesiveness to the skin leaving no residual on the skin after use of the polymer adhesive matrix. US '839 does not teach away from using *aloe vera*, as asserted by applicants. JP '117 teaches *aloe vera* suitable for drugs in general and not specific drugs and not others.

It is well established that the claims are given the broadest interpretation during examination. A conclusion of obviousness under 35 U.S.C. 103 (a) does not require absolute predictability, only a reasonable expectation of success; and references are evaluated by what they suggest to one versed in the art, rather than by their specific disclosure. *In re Bozek*, 163 USPQ 545 (CCPA 1969).

In the light of the foregoing discussion, the Examiner's ultimate legal conclusion is that the subject matter defined by the claims would have been *prima facie* obvious within the meaning of 35 U.S.C. 103 (a).

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 5,356,811 teaches that aloe vera preparation that can effectively employed as a vehicle for active agents because of its the ability to penetrate the skin surface and carry other medication with it is especially useful (col.7, lines 58-61; col.8, lines 1-3). US 6,455,066 teaches topical formulation in the form of patch or monolithic patch comprising local anesthetic in a pressure sensitive adhesive, and aloe vera extract as permeation enhancer (abstract; col.3, lines 10-14; col.5, line 52; col.8, lines 7-10). The patch is inert, non-allergenic, non-toxic, and compatible with the drugs and has rapid onset of action (col.2, lines 61-64). Aloe vera is provided in soy oil base (col.4, lines 55-57).

Conclusion

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis A. Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 7:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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